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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/771,845

02/04/2004

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EXAMINER

RYCKMAN, MELISSA K

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/771,845	Applicant(s) FRAZIER ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-13, 15, 16 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-13, 15, 16 and 48-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/4/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/07 has been entered.

Claim Rejections - 35 USC § 112

Claims 1-7,10-13,15,16 and 48-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Fig. 2A of the application shown the locking element 228 crossing in a diagonal path between 206b and 210b and between 210 and 230, this diagonal path would cut into the tips of the septum primum and the septum secundum, as this would not provide a use of the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 10, 12, 13, 15, 48, 49, and 52 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Peavey et al. (US 2003/0225421).

Regarding Claim 1, Peavey teaches a method of closing a patent foramen ovale having a septum primum (14) and a septum secundum (16), comprising: providing a closure device having a proximal end (26), a distal end (40), a proximal segment (22), an intermediate segment (36, 38) and a distal segment (44), the proximal and intermediate segments defining a first clip-shaped portion and the intermediate and distal segments defining a second clip-shaped portion (figs. 3a and 11), wherein the closure device is self-expandable (para. 55, made of shape memory material) to a deployment shape wherein the proximal, intermediate and distal segments are generally parallel (figs. 3a and 11) to one another; deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in a channel between the septum primum and the septum secundum (fig. 3b); and locking the position of the closure device after deployment (fig. 3b, the device is locked because of the friction provided between the septums and the device) with a locking element (a portion of 22 is a locking element, as this fulfills the function of locking and the structure as provided in the claims); wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together (par. 42).

Regarding Claim 2, Peavey teaches the method of claim 1, wherein the intermediate (38) and distal (44) segments of the closure device when deployed are positioned along surfaces of the septum primum (14) and the proximal (22) and intermediate segments (38) of the closure device when deployed are positioned along surfaces of the septum secundum (16, fig. 3b).

Regarding Claim 3, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions are integrally formed (fig. 3b).

Regarding Claim 4, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions are made of wire (par. 32, proximate lines 1-2).

Regarding Claim 5, Peavey teaches the method of claim 1, wherein the first clip-shaped portion and second clip-shaped portions when the device is deployed forms generally an S-shape (fig. 3a).

Regarding Claim 6, Peavey teaches the method of claim 1, wherein each clip-shaped portion is formed from two adjacent loops connected by a connecting portion (26 is formed by loops 34 and 32, Fig. 2a; 38 is formed by loops 48 and 34 and 36 is formed by 46 and 32; 40 is formed by loops 46 and 48; these are connected with the connecting portion, which is the wire between the loops in Fig. 2a)

Regarding Claim 7, Peavey teaches the method of claim 1, wherein deploying the closure device comprises releasing the closure device from a detachment element (27) provided on the device.

Regarding Claim 10, Peavey teaches a method of closing a patent foramen ovale having a septum primum and a septum secundum, comprising: providing a closure device having a proximal end (26) and a distal end (40) and having a generally elongate configuration (par. 42, lines 2-3) and a clip configuration (fig. 3a), wherein when the device is in its elongate configuration the proximal and distal ends are pulled away from each other and when the closure device is in its clip configuration the device has generally an S-shape (fig. 3a), the closure device being releasably attached relative to a delivery device (para. 55); delivering the closure device to the patent foramen ovale with the delivery device, the closure device being held relative to the delivery device in its elongate configuration; and deploying the closure device in the patent foramen ovale, wherein the closure device when deployed includes a first clip-shaped portion positioned around the septum secundum and a second clip-shaped portion positioned around the septum primum (par. 42, figs. 3b and 11); and locking the closure device in its clip configuration after deployment (fig. 3b, the device is locked because of the friction provided between the septums and the device, according to the applicants specifications, paragraph 112, the lock can be a friction fit) and providing a locking element (a portion of 22 is a locking element, as this fulfills the function of locking and the structure as provided in the claims).

Regarding Claim 12, Peavey teaches the method of claim 10, wherein the closure device is held in its elongate configuration distal to a deployment catheter (for a small amount of time a portion of the closure device is in an elongate configuration, para. 55).

Regarding Claim 13, Peavey teaches the method of claim 10, wherein the closure device is delivered by positioning the catheter between the septum primum and septum secundum (par. 42).

Regarding Claim 15, Peavey teaches the method of claim 10, wherein the closure device self-expands to its deployment configuration (par. 33).

Regarding Claim 48, Peavey teaches the method of claim 1, wherein the intermediate segment comprises at least two side-by-side wire portions (38 includes portions of 48 and 34, and 36 includes portions of 46 and 32).

Regarding Claims 49 and 52, Peavey teaches the locking element is provided as part of the closure device (a portion of 22 is a locking element, as this fulfills the function of locking and the structure as provided in the claims).

Claims 11,16, 50, 51, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peavey in view of Shaw et al. (US 6171329).

Regarding claim 11, Peavey teaches all limitations of preceding dependent claim 10 as previously described, and further teaches wherein the device includes a detachment element (27), but fails to teach wherein the device is delivered using a core wire which releasably engages the detachment element. Shaw teaches a closure device wherein the device includes a detachment element (44) at its proximal end, and the device is delivered using a core wire (42) that releasably engages the detachment element (Fig. 5D).

It would have been obvious to one of ordinary skill in the art to combine Shaw with Peavey, in order to provide exact positioning or repositioning of the device before deployment.

Regarding claim 16, Peavey teaches all limitations of preceding dependent claim 10 as previously described, and further teaches wherein the device includes a detachment element (27), but fails to teach the device includes a plurality of eyelets, and the closure device is releasably attached to the delivery device by engaging a core through at least some of the eyelets. Shaw teaches a device includes a plurality of eyelets (44,46,48), and the closure device is releasably attached to the delivery device by engaging a core through at least some of the eyelets (Fig. 5D).

It would have been obvious to one of ordinary skill in the art to use the eyelets of Shaw with the device of Peavey, because the eyelets help to deliver the device and complete the closure of the wall defect (Shaw, col. 9, ll. 4-8).

Regarding claims 50,51,53 and 54, Peavey teaches a locking element but does not teach the structure as taught in the claims, however Shaw teaches the locking element connects to the proximal and distal ends of the device (42), and locking the position of the closure device after deployment comprises longitudinally shortening and radially expanding the device (Fig. 5D and 5E). Shaw teaches the locking element comprises a locking string (42) connected to eyelets (44,46,48) provided on the closure device.

It would have been obvious to one of ordinary skill in the art to combine Peavey with the locking element of Shaw, as Shaw has the locking element extend from the

proximal and distal ends of the device, as this would provide control over the entire device as shown in Shaw, Fig. 5D. It would have been obvious to one of ordinary skill in the art to use the eyelets of Shaw with the device of Peavey, because the eyelets help to deliver the device and complete the closure of the wall defect (Shaw, col. 9, ll. 4-8).

Response to Arguments

Applicant's arguments filed 12/21/07 have been fully considered but they are not persuasive. The examiner has reviewed the co-pending applications as submitted by the applicant in the arguments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Ryckman whose telephone number is (571)-272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR

/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773